

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Medidata Solutions, Inc. (“Medidata”), by and through its undersigned counsel, hereby files this Complaint against DATATRAK International, Inc. (“DATATRAK”) and avers as follows:

NATURE OF ACTION

1. This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United States of America, 35 U.S.C. § 101, *et seq.*

PARTIES

2. Medidata is a Delaware corporation having its corporate headquarters and a place of business at 79 Fifth Avenue, 8th Floor, New York, New York 10003. Medidata also maintains a place of business at 379 Thornall Street, 15th Floor, Edison, New Jersey 08837. Medidata is a leading global provider of cloud-based clinical development solutions to a diverse life science customer base that includes biopharmaceutical companies, medical device and diagnostic companies, academic and government institutions, and contract research organizations. That customer base includes more than 20 of the top 25 global pharmaceutical companies as well as organizations of all sizes developing life-enhancing medical treatments and diagnostics.

3. On information and belief, DATATRAK is an Ohio corporation, having a place of business at 6150 Parkland Boulevard, Mayfield Heights, Ohio 44124. On information and belief, DATATRAK is a provider of information technology to the clinical trial industry.

4. On information and belief, DATATRAK is the owner of United States Patent No. 8,234,294 (the “294 patent), which is the subject of the declaratory judgment counts of this action.

JURISDICTION AND VENUE

5. This is a civil action regarding allegations of non-infringement and invalidity arising under the patent laws of the United States, Title 35 of the United States Code, in which Medidata seeks declaratory relief under the Declaratory Judgment Act. Thus, this Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

6. A definite and concrete, real and substantial, justiciable controversy exists between Medidata and DATATRAK regarding, *inter alia*, the non-infringement and invalidity of the '294 patent, which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

7. This Court has personal jurisdiction over DATATRAK in that DATATRAK conducts business, including selling services and products, within the state of New Jersey and this judicial district. On information and belief, DATATRAK, directly or through intermediaries, distributes, offers for sale, sells, markets, promotes and/or advertises its products and services in the state of New Jersey and this judicial district. Furthermore, on information and belief, DATATRAK's products and services regularly enter the stream of commerce in the state of New Jersey and this judicial district. As a result, DATATRAK purposefully avails itself of the privilege of doing business in the District of New Jersey. Moreover, by doing business in the District of New Jersey, DATATRAK avails itself of the protections of the District of New Jersey, and in turn, consents to jurisdiction in the District of New Jersey.

8. Venue is proper in this District, *inter alia*, pursuant to 28 U.S.C. §§ 1391 and 1400.

STATEMENT OF FACTS

9. On information and belief, DATATRAK owns multiple United States patents and has stated that it will vigorously protect and enforce those patents. DATATRAK has further indicated that it will specifically direct its protection and enforcement efforts against Medidata.

10. On December 9, 2008, the United States Patent and Trademark Office (“PTO”) issued U.S. Patent No. 7,464,087 (the “’087 Patent”), entitled “Method and System of Unifying Data,” to DATATRAK, the assignee of named inventors Marc J. Shlaes, Jochen van Berkel, Hermann Engel and Mario Jugel.

11. On information and belief, DATATRAK is the current assignee of the ’087 patent.

12. On March 4, 2011, DATATRAK filed a complaint for alleged patent infringement against Medidata in *DATATRAK International, Inc. v. Medidata Solutions, Inc.*, No. 1:11-cv-00458, in the U.S. District Court for the Northern District of Ohio. The complaint accuses Medidata of infringing the ’087 patent.

13. Medidata filed a request for *ex parte* reexamination of the ’087 patent on October 28, 2011, which resulted in a stay of the pending litigation between DATATRAK and Medidata on December 16, 2011. The reexamination proceeding is currently pending.

14. On July 31, 2012, the PTO issued the ’294 patent, entitled “Method and System of Unifying Data,” to DATATRAK, the assignee of named inventors Marc J. Shlaes, Jochen van Berkel, Hermann Engel and Mario Jugel.

15. The ’294 patent is a divisional of the ’087 patent and shares many similarities with the ’087 patent.

16. The '294 patent shares the same title, specification, and inventors as the '087 patent. The '294 patent is also subject to a terminal disclaimer that was filed to overcome a double patenting rejection issued by the PTO in view of the '087 patent.

17. On information and belief, DATATRAK is the current assignee of the '294 patent.

18. DATATRAK has made public statements that it intends to vigorously enforce its patent rights against Medidata, both with respect to its '087 patent and its other intellectual property.

19. In DATATRAK's Quarterly Report dated March 31, 2012, it stated, "The Company [DATATRAK] recently received a final office action from the U.S. Patent and Trademark Office rejecting the claims of the patent-in-suit. The Company intends to contest such office action. Although there can be no assurance as to the final outcome of the reexamination process, the Company intends to continue to vigorously protect its intellectual property, including any applicable claims against Medidata after the conclusion of the patent reexamination process."

20. In DATATRAK's most recent Annual Report, dated December 31, 2011, the company stated, "Although there can be no assurance as to the outcome of the reexamination process, the Company intends to resume vigorous prosecution of its claims against Medidata after the conclusion of the present reexamination process."

21. Given DATATRAK's initiation of litigation against Medidata to enforce the '087 patent, the many similarities between the '087 patent and the '294 patent, and DATATRAK's public statements that it will vigorously protect and enforce its intellectual property rights against

Medidata, which include the '294 patent, it is manifest that DATATRAK intends to pursue litigation against Medidata asserting infringement of the '294 patent.

FIRST COUNT

(Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,234,294)

22. Medidata hereby repeats, re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 21 above as though fully stated herein.

23. A definite and concrete, real and substantial, justiciable controversy exists between Medidata and DATATRAK regarding, *inter alia*, the non-infringement of any valid claim of the '294 patent, which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

24. Medidata has not infringed and does not infringe any valid claim of the '294 patent.

25. Accordingly, Medidata seeks a judgment declaring that it does not infringe and has not infringed, directly or indirectly, contributorily or by inducement, any valid claim of the '294 patent.

SECOND COUNT

(Declaratory Judgment of Invalidity of U.S. Patent No. 8,234,294)

26. Medidata hereby repeats, re-alleges and incorporates by reference each and every allegation contained in paragraphs 1 through 25 above as though fully stated herein.

27. A definite and concrete, real and substantial, justiciable controversy exists between Medidata and DATATRAK regarding, *inter alia*, the invalidity of the claims of the '294 patent, which is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

28. The claims of the '294 patent are invalid for failure to comply with one or more of the requirements of patentability set forth in Title 35 of the United States Code or the rules, regulations and laws related thereto, including without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103 and/or 112.

29. Accordingly, Medidata seeks a judgment declaring that the claims of the '294 patent are invalid, void and of no legal consequence.

PRAYER FOR RELIEF

WHEREFORE, Medidata prays for a judgment in its favor, including:

- A. A declaration that Medidata has not infringed, and is not infringing, any valid claim of the '294 patent;
- B. A declaration that each of the claims of the '294 patent is invalid, void and of no legal consequence;
- C. An injunction prohibiting DATATRAK, its officers, directors, servants, managers, employees, agents, successors and assignees, and all persons in active concert or participation with them, from alleging infringement of the '294 patent against Medidata;
- D. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285;
- E. An award of Medidata's reasonable attorneys' fees, costs and expenses; and
- F. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b), Fed. R. Civ. P., Medidata demands a trial by jury of all issues triable as of right to a jury.

Dated: July 31, 2012

SAIBER LLC

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Plaintiff Medidata Solutions, Inc., by its undersigned counsel, hereby certifies pursuant to Local Civil Rule 11.2 that the matter in controversy in this case is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceedings.

Dated: July 31, 2012

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Under Local Civil Rule 201.1, Plaintiff Medidata Solutions, Inc., by its undersigned counsel, hereby certifies that Medidata Solutions, Inc. seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: July 31, 2012

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